DEPARTMEN

Office of the Secretary

21 CFR Ch. I

25 CFR Ch. V

42 CFR Chs. I-V

45 CFR Subtitle A; Subtitle B, Chs. II, III, and XIII

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual Regulatory Agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order (EO) 12866 require the semiannual issuance of an inventory of rulemaking actions under development throughout the Department, offering for public review summarized information about forthcoming regulatory actions.

FOR FURTHER INFORMATION CONTACT: Kashif Syed, Senior Advisor to the Executive Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; (202) 690-5627.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) is the Federal government's lead agency for protecting the health of all Americans and providing essential human services. HHS enhances the health and well-being of Americans by promoting effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

This Agenda presents the regulatory activities that the Department expects to undertake in the foreseeable future to advance this mission. The purpose of the Agenda is to encourage more effective public participation in the regulatory process. The regulatory actions forecasted in this Agenda reflect the priorities of HHS Secretary Xavier Becerra and the Biden-Harris Administration. Accordingly, this Agenda contains rulemakings aimed at tackling the coronavirus disease 2019 (COVID-19) pandemic, building and

expanding access to affordable health care, addressing health disparities and promoting equity, and boosting the wellbeing of children and families, among other policy priorities.

The rulemaking abstracts included in this paper issue of the **Federal Register** cover, as required by the Regulatory Flexibility Act of 1980, those prospective HHS rulemakings likely to have a significant economic impact on a substantial number of small entities. The Department's complete Regulatory Agenda is accessible online at http://www.RegInfo.gov.

Kashif Syed,

Senior Advisor to the HHS Executive Secretary.

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
84	Limiting the Effect of Exclusions Implemented Under the Social Security Act **(Rulemaking Resulting From a Section 610 Review)**	0991-AC11

Substance Abuse and Mental Health Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
85	Treatment of Opioid use Disorder With Extended Take Home Doses of Methadone	0930-AA39

Centers for Disease Control and Prevention—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
86	Control of Communicable Diseases; Foreign Quarantine	0920-AA75

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
87	National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers	0910-AH11
88	Medication Guide; Patient Medication Information	0910-AH68
89	Requirements for Tobacco Product Manufacturing Practice	0910-AH91
90	Administrative Detention of Tobacco Products	0910-AI05
91	Nutrient Content Claims, Definition of Term: Healthy	0910-AI13
92	Tobacco Product Standard for Characterizing Flavors in Cigars	0910-AI28
93	Conduct of Analytical and Clinical Pharmacology, Bioavailability and Bioequivalence Studies	0910-AI57
94	Amendments to the Final Rule Regarding the List of Bulk Substances That Can Be Used to Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug and Cosmetic Act **(Section 610 Review)**	0910-AI70
95	Distribution of Compounded Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act **(Section 610 Review)**	0910-AI71

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number

96	Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, Neutral Manner in Advertisements in Television and Radio Format	0910-AG27
97	Sunlamp Products; Amendment to the Performance Standard	0910-AG30
98	Mammography Quality Standards Act	0910-AH04
99	Amendments to the List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act	0910-AH81
100	Revocation of Uses of Partially Hydrogenated Oils in Foods	0910-AI15
101	Requirements For Additional Traceability Records For Certain Foods	0910-AI44

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
102	General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products	0910-AH14
103	Nicotine Toxicity Warnings	0910-AH24
104	Certain Requirements Regarding Prescription Drug Marketing (203 Amendment)	0910-AH56
105	Postmarketing Safety Reporting Requirements, Pharmacovigilance Plans, and Pharmacovigilance Quality Systems for Human Drug and Biological Products	0910-AI61

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number

106	Laboratory Accreditation for Analyses of Foods	0910-AH31

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
107	Administrative Simplification: Modifications to NCPDP Retail Pharmacy Standards (CMS-0056)	0938-AU19
108	Medicare Advantage and Medicare Prescription Drug Benefit Program Payment Policy (CMS-4198)	0938-AU59
109	CY 2023 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1770) **(Section 610 Review)**	0938-AU81
110	CY 2023 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1772) **(Section 610 Review)**	0938-AU82
111	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2023 Rates (CMS-1771) **(Section 610 Review)**	0938-AU84
112	Transitional Coverage for Emerging Technologies (CMS-3421)	0938-AU86
113	Conditions of Participation (CoPs) for Rural Emergency Hospitals (REHs) and Critical Access Hospital (CAH) COP Updates (CMS-3419) **(Section 610 Review)**	0938-AU92

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
114	Requirements Related to Surprise Billing; Part II (CMS-9908)	0938-AU62

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
115	Omnibus COVID-19 Health Care Staff Vaccination (CMS-3415) **(Section 610 Review)**	0938-AU75

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
116	Durable Medical Equipment Fee Schedule, Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Non-Competitive Bidding Areas (CMS-1687) **(Completion of a Section 610 Review)**	0938-AT21
117	Most Favored Nation (MFN) Model (CMS-5528) **(Completion of a Section 610 Review)**	0938-AT91
118	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2022 Rates (CMS-1752) **(Completion of a Section 610 Review)**	0938-AU44

Department of Health and Human Services (HHS)	**Proposed Rule Stage**
Office of the Secretary (OS)	

84. LIMITING THE EFFECT OF EXCLUSIONS IMPLEMENTED UNDER THE SOCIAL SECURITY ACT (RULEMAKING RESULTING FROM A SECTION 610 REVIEW) [0991-AC11]

Legal Authority: 5 U.S.C. 301; 31 U.S.C. 6101

Abstract: Exclusions implemented under the Social Security Act prevent individuals convicted of certain crimes or individuals whose health care licenses have been revoked from participating in Federal health care programs. Instead of only being barred from participating in all Federal healthcare programs, certain regulatory provisions have resulted in these type of exclusion actions being given an overly broad government-wide effect, and excluded parties have been barred from participating in all Federal procurement and non-procurement actions. However, because Social Security Act exclusions are not issued under an agency's suspension and debarment authority, they do not stop individuals from participating in all Federal procurement and non-procurement actions. For an agency to bar individuals from participating in all procurement and non-procurement activities, it must exercise its suspension and debarment authority under the Federal Acquisition Regulation or the Nonprocurement Common Rule. This rulemaking would remove the regulatory provisions at issue, in order to align the regulation with the intent of the Social Security Act and current practice.

Timetable:

Action	Date	FR Cite
NPRM	08/00/22	

Regulatory Flexibility Analysis Required: No

Agency Contact: Tiffani Redding, Program Analyst, Department of Health and Human Services, Office of the Secretary, 200 Independence Avenue SW, Washington, DC 20201

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RIN: 0991-AC11

Department of Health and Human Services (HHS)	Proposed Rule Stage
Substance Abuse and Mental Health Services Administration (SAMHSA)	

85. TREATMENT OF OPIOID USE DISORDER WITH EXTENDED TAKE HOME DOSES OF METHADONE [0930-AA39]

Legal Authority: 21 U.S.C. sec. 823(g)(1)

Abstract: SAMHSA will propose to revise 42 CFR part 8 to make permanent some regulatory flexibilities for opioid treatment programs to provide extended take home doses of methadone. To facilitate this new treatment paradigm, sections of 42 CFR part 8 would require updating to reflect current treatment practice. SAMHSA's changes would impact roughly 1800 opioid treatment programs and state opioid treatment authorities.

Timetable:

Action	Date	FR Cite
NPRM	09/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Dr. Neeraj Gandotra, Chief Medical Officer, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, 18E67, Rockville, MD 20857

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RIN: 0930-AA39

Department of Health and Human Services (HHS)	Final Rule Stage
Centers for Disease Control and Prevention (CDC)	

86. CONTROL OF COMMUNICABLE DISEASES; FOREIGN QUARANTINE [0920-AA75]

Legal Authority: 42 U.S.C. 264; 42 U.S.C. 265

Abstract: This rulemaking amends current regulation to enable CDC to require airlines to collect and provide to CDC certain data elements regarding passengers and crew arriving from foreign countries under certain circumstances.

Timetable:

Action	Date	FR Cite
Interim Final Rule Effective	02/07/20	

Interim Final Rule	02/12/20	85 FR 7874
Interim Final Rule Comment Period End	03/13/20	
Final Action	05/00/23	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ashley C. Altenburger JD, Public Health Analyst, Department of Health and Human Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS: H 16-4, Atlanta, GA 30307

Phone: 800 232-4636

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RIN: 0920-AA75

Department of Health and Human Services (HHS)	**Proposed Rule Stage**
Food and Drug Administration (FDA)	

87. NATIONAL STANDARDS FOR THE LICENSURE OF WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS PROVIDERS [0910-AH11]

Legal Authority: secs. 583 and 584 of the FD&C Act, as added by the DSCSA under Pub. L. 113-54, together with related FD&C Act authority added by the DSCSA.

Abstract: The rulemaking, once finalized and effective, will establish national standards for State licensing of prescription drug wholesale distributors and third-party logistics providers. The rulemaking will also establish a Federal system for wholesale drug distributor and third-party logistics provider licensing for use in the absence of a State licensure program.

Timetable:

Action	**Date**	**FR Cite**
NPRM	02/04/22	87 FR 6708
NPRM Comment Period Extended	05/24/22	87 FR 31439

NPRM Comment Period End	06/06/22	
NPRM Comment Extended End	09/06/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Aaron Weisbuch, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 4261, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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Email: aaron.weisbuch@fda.hhs.gov

RIN: 0910-AH11

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88. MEDICATION GUIDE; PATIENT MEDICATION INFORMATION [0910-AH68]

Legal Authority: 21 U.S.C. 321 et seq.; 42 U.S.C. 262; 42 U.S.C. 264; 21 U.S.C. 371

Abstract: The proposed rule would amend FDA medication guide regulations to require a new form of patient labeling, Patient Medication Information, for submission to and review by FDA for human prescription drug products and certain blood products used, dispensed, or administered on an outpatient basis. The proposed rule would include requirements for Patient Medication Information development and distribution. The proposed rule would require clear and concisely written prescription drug product information presented in a consistent and easily understood format to help patients use their prescription drug products safely and effectively.

Timetable:

Action	Date	FR Cite
NPRM	10/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Chris Wheeler, Supervisory Project Manager, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 3330, Silver Spring, MD 20993

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RIN: 0910-AH68

89. REQUIREMENTS FOR TOBACCO PRODUCT MANUFACTURING PRACTICE [0910-AH91]

Legal Authority: 21 U.S.C. 371; 21 U.S.C. 387b; 21 U.S.C. 387f

Abstract: The rule is proposing to establish tobacco product manufacturing practice (TPMP) requirements for manufacturers of finished and bulk tobacco products. This proposed rule, if finalized, would set forth requirements for the manufacture, pre-production design validation, packing, and storage of a tobacco product. This proposal would help prevent the manufacture and distribution of contaminated and otherwise nonconforming tobacco products. This proposed rule provides manufacturers with flexibility in the manner in which they comply with the proposed requirements while giving FDA the ability to enforce regulatory requirements, thus helping to assure the protection of public health.

Timetable:

Action	Date	FR Cite
NPRM	07/00/22	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910-AH91

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90. ADMINISTRATIVE DETENTION OF TOBACCO PRODUCTS [0910-AI05]

Legal Authority: 21 U.S.C. 334; 21 U.S.C. 371

Abstract: FDA is proposing regulations to establish requirements for the administrative detention of tobacco products. This proposal would allow FDA to administratively detain tobacco products encountered during inspections of manufacturers or other establishments that manufacture, process, pack, or hold tobacco products that an authorized FDA representative conducting the inspection has reason to believe are adulterated or misbranded. The intent of administrative detention is to protect public health by preventing the distribution or use of tobacco products encountered during inspections that are believed to be adulterated or misbranded until FDA has had time to consider the appropriate action to take and, where appropriate, to initiate legal action.

Timetable:

Action	Date	FR Cite
NPRM	12/00/22	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910-AI05

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91. NUTRIENT CONTENT CLAIMS, DEFINITION OF TERM: HEALTHY [0910-AI13]

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 343; 21 U.S.C. 371

Abstract: The proposed rule would update the definition for the implied nutrient content claim "healthy" to be consistent with current nutrition science and federal dietary guidelines. The proposed rule would revise the requirements for when the claim "healthy" can be voluntarily used in the labeling of human food products so that the claim reflects current science and dietary guidelines and helps consumers maintain healthy dietary practices.

Timetable:

Action	Date	FR Cite
NPRM	06/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Vincent De Jesus, Nutritionist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, (HFS-830), Room 3D-031, 5100 Paint Branch Parkway, College Park, MD 20740

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RIN: 0910-AI13

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92. TOBACCO PRODUCT STANDARD FOR CHARACTERIZING FLAVORS IN CIGARS [0910-AI28]

Legal Authority: 21 U.S.C. 331; 21 U.S.C. 333; 21 U.S.C. 371(a); 21 U.S.C. 387b and 387c; 21 U.S.C. 387f(d) and 387g; ...

Abstract: Evidence shows that flavored tobacco products appeal to youth and also shows that youth may be more likely to initiate tobacco use with such products. Characterizing flavors in cigars, such as strawberry, grape, orange, and cocoa, enhance taste and make them easier to use. Over a half million youth in the United States use flavored cigars, placing these youth at risk for cigar-related disease and death. This proposed rule is a tobacco product standard that would prohibit characterizing flavors (other than tobacco) in all cigars. We are taking this action with the intention of reducing the tobacco-related death and disease associated with cigar use.

Timetable:

Action	Date	FR Cite
ANPRM	03/21/18	83 FR 12294
ANPRM Comment Period End	07/19/18	
NPRM	05/04/22	87 FR 26396
NPRM Comment Period End	07/05/22	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910-AI28

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93. CONDUCT OF ANALYTICAL AND CLINICAL PHARMACOLOGY, BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES [0910-AI57]

Legal Authority: 21 U.S.C. 355; 21 U.S.C. 371; 21 U.S.C. 374; 42 U.S.C. 262

Abstract: FDA is proposing to amend 21 CFR 320, in certain parts, and establish a new 21 CFR 321 to clarify FDA's study conduct expectations for analytical and clinical pharmacology, bioavailability (BA) and bioequivalence (BE) studies that support marketing applications for human drug and biological products. The proposed rule would specify needed basic study conduct requirements to enable FDA to ensure those studies are conducted appropriately and to verify the reliability of study data from those studies. This regulation would align with FDA's other good practice regulations, would also be consistent with current industry best practices, and would harmonize the regulations more closely with related international regulatory expectations.

Timetable:

Action	Date	FR Cite
NPRM	12/00/22	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910-AI57

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94. AMENDMENTS TO THE FINAL RULE REGARDING THE LIST OF BULK SUBSTANCES THAT CAN BE USED TO COMPOUND DRUG PRODUCTS IN ACCORDANCE WITH SECTION 503A OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT (SECTION 610 REVIEW) [0910-AI70]

Legal Authority: 21 U.S.C. 353a; 21 U.S.C. 351; 21 U.S.C. 371(a); 21 U.S.C. 352; 21 U.S.C. 355; ...

Abstract: FDA has issued a regulation creating a list of bulk drug substances (active pharmaceutical ingredients) that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), although they are neither the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph nor components of FDA-approved drug products (the 503A Bulks List). The proposed rule will identify certain bulk drug substances that FDA has considered and is proposing to place on the 503A Bulks List and certain bulk drug substances that FDA has considered and is proposing not to include on the 503A Bulks List.

Timetable:

Action	Date	FR Cite
NPRM	03/00/23	

Regulatory Flexibility Analysis Required: Yes

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Phone: 240 402-4078

RIN: 0910-AI70

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95. • DISTRIBUTION OF COMPOUNDED DRUG PRODUCTS UNDER SECTION 503A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (SECTION 610 REVIEW) [0910-AI71]

Legal Authority: 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 353a; 21 U.S.C. 353a-1; 21 U.S.C. 353b; 21 U.S.C. 355; 21 U.S.C. 371

Abstract: The Food and Drug Administration is proposing rulemaking regarding statutory requirements for certain distributions of compounded human prescription drug products. The proposed rule, if finalized, will include provisions regarding a standard memorandum of understanding (MOU) that describes the responsibilities of a State Board of Pharmacy or other appropriate State agency that chooses to sign the standard MOU in investigating complaints related to drug products compounded in such State and distributed outside such State and in addressing the interstate distribution of inordinate amounts of

compounded human drug products. It will also, if finalized, include provisions regarding the statutory 5 percent limit on distribution of compounded human drug products out of the State in which they are compounded in States that do not sign the standard MOU, and may address adverse event reporting, product quality reporting, and communication with State boards of pharmacy.

Timetable:

Action	Date	FR Cite
NPRM	12/00/22	

Regulatory Flexibility Analysis Required: Undetermined

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RIN: 0910-AI71

Department of Health and Human Services (HHS)	Final Rule Stage
Food and Drug Administration (FDA)	

96. DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISEMENTS: PRESENTATION OF THE MAJOR STATEMENT IN A CLEAR, CONSPICUOUS, NEUTRAL MANNER IN ADVERTISEMENTS IN TELEVISION AND RADIO FORMAT [0910-AG27]

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 352; 21 U.S.C. 355; 21 U.S.C. 360b; 21 U.S.C. 371; ...

Abstract: The Food and Drug Administration (FDA) is amending its regulations concerning direct-to-consumer (DTC) advertisements of prescription drugs. Prescription drug advertisements presented through media such as TV and radio must disclose the product's major side effects and contraindications in what is sometimes called the major statement. The rule would revise the regulation to reflect the statutory requirement that in DTC advertisements for human drugs in television or radio format, the major statement relating to side effects and contraindications of an advertised prescription drug must be

presented in a clear, conspicuous, and neutral manner. This rule also establishes standards for determining whether the major statement in these advertisements is presented in the manner required.

Timetable:

Action	Date	FR Cite
NPRM	03/29/10	75 FR 15376
NPRM Comment Period End	06/28/10	
NPRM Comment Period Reopened	01/27/12	77 FR 4273
NPRM Comment Period End	02/27/12	
NPRM Comment Period Reopened	03/29/12	77 FR 16973
NPRM Comment Period Reopened End	04/09/12	
Final Rule	05/00/23	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Suzanna Boyle, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 51, Room 3214, Silver Spring, MD 20993

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RIN: 0910-AG27

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97. SUNLAMP PRODUCTS; AMENDMENT TO THE PERFORMANCE STANDARD [0910-AG30]

Legal Authority: 21 U.S.C. 360ii; 21 U.S.C. 360kk; 21 U.S.C. 393; 21 U.S.C. 371

Abstract: FDA is updating the performance standard for sunlamp products and ultraviolet lamps for use in these products to improve safety, reflect new scientific information, and work towards harmonization with international standards. By harmonizing with the International Electrotechnical Commission, this rule will decrease the regulatory burden on industry and allow the Agency to take advantage of the expertise of the international committees, thereby also saving resources.

Timetable:

Action	Date	FR Cite
NPRM	12/22/15	80 FR 79505
NPRM Comment Period End	03/21/16	
Final Rule	12/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ian Ostermiller, Regulatory Counsel, Center for Devices and Radiological Health, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 66, Room 5454, Silver Spring, MD 20993

Phone: 301 796-5678

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RIN: 0910-AG30

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98. MAMMOGRAPHY QUALITY STANDARDS ACT [0910-AH04]

Legal Authority: 21 U.S.C. 360i; 21 U.S.C. 360nn; 21 U.S.C. 374(e); 42 U.S.C. 263b

Abstract: FDA is amending its regulations governing mammography. The amendments will update the regulations issued under the Mammography Quality Standards Act of 1992 (MQSA) and the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA is taking this action to address changes in mammography technology and mammography processes that have occurred since the regulations were published in 1997 and to address breast density reporting to patient and healthcare providers.

Timetable:

Action	Date	FR Cite
NPRM	03/28/19	84 FR 11669
NPRM Comment Period End	06/26/19	
Final Rule	09/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Laurie Sternberg, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 66, Room 5517, Silver Spring, MD 20993

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RIN: 0910-AH04

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99. AMENDMENTS TO THE LIST OF BULK DRUG SUBSTANCES THAT CAN BE USED TO COMPOUND DRUG PRODUCTS IN ACCORDANCE WITH SECTION 503A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT [0910-AH81]

Legal Authority: 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 353a; 21 U.S.C. 355; 21 U.S.C. 371; ...

Abstract: FDA has issued a regulation creating a list of bulk drug substances (active pharmaceutical ingredients) that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), although they are neither the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph nor components of FDA-approved drugs (the 503A Bulks List). FDA has proposed to amend the 503A Bulks List by placing five additional bulk drug substances on the list. FDA has also identified 26 bulk drug substances that FDA has considered and proposed not to include on the 503A Bulks List. Additional substances nominated by the public for inclusion on this list are currently under consideration and will be the subject of a future rulemaking.

Timetable:

Action	Date	FR Cite
NPRM	09/05/19	84 FR 46688
NPRM Comment Period End	12/04/19	
Final Rule	03/00/23	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Rosilend Lawson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 5197, Silver Spring, MD 20993

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RIN: 0910-AH81

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100. REVOCATION OF USES OF PARTIALLY HYDROGENATED OILS IN FOODS [0910-AI15]

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 341; 21 U.S.C. 342; 21 U.S.C. 343; 21 U.S.C. 348; 21 U.S.C. 371; 21 U.S.C. 379e

Abstract: In the **Federal Register** of June 17, 2015 (80 FR 34650), we published a declaratory order announcing our final determination that there is no longer a consensus among qualified experts that partially hydrogenated oils (PHOs) are generally recognized as safe (GRAS) for any use in human food. In the **Federal Register** of May 21, 2018 (83 FR 23382), we denied a food additive petition requesting that the food additive regulations be amended to provide for the safe use of PHOs in certain food applications. We are now planning to issue a direct final rule and companion proposed rule to update our regulations to remove all mention of partially hydrogenated oils from FDA's GRAS regulations and as an optional ingredient in standards of identity. We are also revoking all prior sanctions for uses of PHOs in food.

Timetable:

Action	Date	FR Cite
Direct Final Rule	10/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ellen Anderson, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS-265, 4300 River Road, College Park, MD 20740

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RIN: 0910-AI15

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101. REQUIREMENTS FOR ADDITIONAL TRACEABILITY RECORDS FOR CERTAIN FOODS [0910-AI44]

Legal Authority: sec. 204 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) (21 U.S.C. 2223(d)); sec. 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(a)); sec. 361 of the Public Health Service Act (42 U.S.C. 264)

Abstract: This rule will establish additional recordkeeping requirements for facilities that manufacture, process, pack, or hold foods that are designated as high-risk foods.

Timetable:

Action	Date	FR Cite
NPRM	09/23/20	85 FR 59984
NPRM Comment Period End	01/21/21	
NPRM Comment Period Extended	12/18/20	85 FR 82393
NPRM Comment Period End	02/22/21	
Final Rule	11/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Katherine Vierk, Director, Division of Public Health Informatics and Analytics, Department of Health and Human Services, Food and Drug Administration, 5001 Campus Drive, CPK1, Room 2B014, HFS-005, College Park, MD 20740

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RIN: 0910-AI44

Department of Health and Human Services (HHS)	Long-Term Actions
Food and Drug Administration (FDA)	

102. GENERAL AND PLASTIC SURGERY DEVICES: RESTRICTED SALE, DISTRIBUTION, AND USE OF SUNLAMP PRODUCTS [0910-AH14]

Legal Authority: 21 U.S.C. 360j(e)

Abstract: This rule will apply device restrictions to sunlamp products. Sunlamp products include ultraviolet (UV) lamps and UV tanning beds and booths. The incidence of skin cancer, including melanoma, has been increasing, and a large number of skin cancer cases are attributable to the use of

sunlamp products. The devices may cause about 400,000 cases of skin cancer per year, and 6,000 of which are melanoma. Beginning use of sunlamp products at young ages, as well as frequently using sunlamp products, both increases the risk of developing skin cancers and other illnesses, and sustaining other injuries. Even infrequent use, particularly at younger ages, can significantly increase these risks.

Timetable:

Action	Date	FR Cite
NPRM	12/22/15	80 FR 79493
NPRM Comment Period End	03/21/16	
Final Rule	06/00/23	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ian Ostermiller, Regulatory Counsel, Center for Devices and Radiological Health, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 66, Room 5454, Silver Spring, MD 20993

Phone: 301 796-5678

Email: ian.ostermiller@fda.hhs.gov

RIN: 0910-AH14

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103. NICOTINE TOXICITY WARNINGS [0910-AH24]

Legal Authority: 21 U.S.C. 301 et seq.; 21 U.S.C. 331; 21 U.S.C. 371; 21 U.S.C. 387f; ...

Abstract: This rule would establish acute nicotine toxicity warning requirements for liquid nicotine and nicotine-containing e-liquid(s) that are made or derived from tobacco and intended for human consumption, and potentially for other tobacco products including, but not limited to, novel tobacco products such as dissolvables, lotions, gels, and drinks. This action is intended to increase consumer awareness and knowledge of the risks of acute toxicity due to accidental nicotine exposure from nicotine-containing e-liquids in tobacco products.

Timetable:

Action	Date	FR Cite
NPRM	10/00/23	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Courtney Smith, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G3355, Silver Spring, MD 20993

Phone: 877 287-1373

Email: ctpregulations@fda.hhs.gov

RIN: 0910-AH24

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104. CERTAIN REQUIREMENTS REGARDING PRESCRIPTION DRUG MARKETING (203 AMENDMENT) [0910-AH56]

Legal Authority: Section 503 and related provisions of the FD&C Act, as amended by Pub. L. 113-54

Abstract: The Food and Drug Administration (FDA) is amending the regulations at 21 CFR 203 to remove provisions no longer in effect and incorporate conforming changes following enactment of the Drug Supply Chain Security Act (DSCSA). In this proposed rulemaking, the Agency is amending the regulations to clarify provisions and avoid causing confusion with the new standards for wholesale distribution established by DSCSA.

Timetable:

Action	Date	FR Cite
NPRM	02/04/22	87 FR 6443
NPRM Comment Period End	04/05/22	
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Aaron Weisbuch, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 4261, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796-9362

Email: aaron.weisbuch@fda.hhs.gov

RIN: 0910-AH56

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105. POSTMARKETING SAFETY REPORTING REQUIREMENTS, PHARMACOVIGILANCE PLANS, AND PHARMACOVIGILANCE QUALITY SYSTEMS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS [0910-AI61]

Legal Authority: 42 U.S.C 262; 42 U.S.C. 264; 42 U.S.C. 300aa-25; 21 U.S.C. 321; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371; 21 U.S.C. 374; ...

Abstract: The proposed rule would modernize FDA's regulations on postmarketing safety reporting and pharmacovigilance for human drug and biological products, including blood and blood components, by capturing important new safety-related information, improving the quality and utility of submitted reports, and supporting enhanced alignment with internationally harmonized reporting guidelines. Among other things, the proposed rule would require the submission of certain nonclinical and clinical data to FDA in a periodic safety report, rather than the annual report. The proposed rule also would require application holders for drug products and certain biological products to establish and maintain a pharmacovigilance quality system that reflects the application holder's unique needs and that may support a more streamlined, flexible approach to satisfying certain postmarketing safety reporting requirements.

Timetable:

Action	Date	FR Cite
NPRM	11/00/23	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Janice L. Weiner, Principal Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Building 51, Room 6270, Silver Spring, MD 20993-0002

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RIN: 0910-AI61

Department of Health and Human Services (HHS)	Completed Actions
Food and Drug Administration (FDA)	

106. LABORATORY ACCREDITATION FOR ANALYSES OF FOODS [0910-AH31]

Legal Authority: 21 U.S.C. 350k; 21 U.S.C. 371(a); ...

Abstract: This rule will enable FDA to recognize accreditation bodies that will accredit laboratories to perform analyses of food under certain circumstances to help ensure appropriate use of equipment, personnel, and procedures to conduct reliable analyses. A program for accredited laboratories will increase the number of qualified laboratories eligible to perform testing of food, which will help FDA improve the safety of the U.S. food supply.

Completed:

Reason	Date	FR Cite
Final Rule	12/03/21	86 FR 68728
Final Rule Effective	02/01/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Stacie Hammack

Phone: 301 796-5817

Email: stacie.hammack@fda.hhs.gov

RIN: 0910-AH31

Department of Health and Human Services (HHS)	Proposed Rule Stage
Centers for Medicare & Medicaid Services (CMS)	

107. ADMINISTRATIVE SIMPLIFICATION: MODIFICATIONS TO NCPDP RETAIL PHARMACY STANDARDS (CMS-0056) [0938-AU19]

Legal Authority: 42 U.S.C. 1320d to 1320d-9

Abstract: This proposed rule would require pharmacies and vendors to modify the currently adopted National Council for Prescription Drug Programs (NCPDP) standards to the Telecommunications Standard Implementation Guide Version F6 (F6); Batch Standard Implementation Guide version 15; and Batch Standard Subrogation Implementation Guide version 10.

Timetable:

Action	Date	FR Cite
NPRM	09/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Geanelle Herring, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Burden Reduction and Health Informatics, MS: S2-26-17, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4466

Email: geanelle.herring@cms.hhs.gov

RIN: 0938-AU19

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108. MEDICARE ADVANTAGE AND MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAM PAYMENT POLICY (CMS-4198) [0938-AU59]

Legal Authority: 42 U.S.C. 1395w

Abstract: This proposed rule would codify long-established Medicare Advantage and Part D payment policies that are outside the scope of the annual Advance Notice/Rate Announcement.

Timetable:

Action	Date	FR Cite
NPRM	12/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Jennifer Shapiro, Director, Medicare Plan Payment Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C1-13-18, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-7407

Email: jennifer.shapiro@cms.hhs.gov

RIN: 0938-AU59

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109. CY 2023 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS-1770) (SECTION 610 REVIEW) [0938-AU81]

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual proposed rule would revise payment polices under the Medicare physician fee schedule, and make other policy changes to payment under Medicare Part B. These changes would

apply to services furnished beginning January 1, 2023. Additionally, this rule proposes updates to the Quality Payment Program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Gift Tee, Director, Division of Physician Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, 7500 Security Boulevard, MS: C1-09-07, Baltimore, MD 21244

Phone: 410 786-9316

Email: gift.tee@cms.hhs.gov

RIN: 0938-AU81

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110. CY 2023 HOSPITAL OUTPATIENT PPS POLICY CHANGES AND PAYMENT RATES AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS-1772) (SECTION 610 REVIEW) [0938-AU82]

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual proposed rule would revise the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The proposed rule describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule proposes changes to the ambulatory surgical center payment system list of services and rates. This proposed rule would also update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Elise Barringer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4-03-06, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938-AU82

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111. HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS; THE LONG-TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM; AND FY 2023 RATES (CMS-1771) (SECTION 610 REVIEW) [0938-AU84]

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual final rule revises the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This rule implements changes arising from our continuing experience with these systems. In addition, the rule establishes new requirements or revises existing requirements for quality reporting by specific Medicare providers.

Timetable:

Action	Date	FR Cite
NPRM	05/10/22	87 FR 28108
NPRM Comment Period End	06/17/22	
Final Action	10/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Donald Thompson, Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4-01-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6504

Email: donald.thompson@cms.hhs.gov

RIN: 0938-AU84

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112. TRANSITIONAL COVERAGE FOR EMERGING TECHNOLOGIES (CMS-3421) [0938-AU86]

Legal Authority: 42 U.S.C. 263a; 42 U.S.C. 405(a); 42 U.S.C. 1302; 42 U.S.C. 1320b-12; ...

Abstract: This proposed rule would establish the criteria for an expedited coverage pathway to provide Medicare beneficiaries with faster access to innovative and beneficial technologies.

Timetable:

Action	Date	FR Cite
NPRM	04/00/23	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Lori Ashby, Senior Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, MS: S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6322

Email: lori.ashby@cms.hhs.gov

RIN: 0938-AU86

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113. CONDITIONS OF PARTICIPATION (COPS) FOR RURAL EMERGENCY HOSPITALS (REHS) AND CRITICAL ACCESS HOSPITAL (CAH) COP UPDATES (CMS-3419) (SECTION 610 REVIEW) [0938-AU92]

Legal Authority: 42 U.S.C. 1395x

Abstract: This proposed rule would establish health and safety requirements for a new provider type, Rural Emergency Hospitals, in accordance with section 125 of the Consolidated Appropriations Act, 2021.

Timetable:

Action	Date	FR Cite
NPRM	06/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Kianna Banks, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, MS: S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938-AU92

Department of Health and Human Services (HHS)	Final Rule Stage
Centers for Medicare & Medicaid Services (CMS)	

114. REQUIREMENTS RELATED TO SURPRISE BILLING; PART II (CMS-9908) [0938-AU62]

Legal Authority: Pub. L. 116-260, Division BB, title I and title II

Abstract: This final rule implements provisions related to the independent dispute resolution processes included in the Public Health Service Act sections 2799A-1(c) and 2799A-2(b), as added by sections 103 and 105 of the No Surprises Act.

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/07/21	86 FR 55980
Interim Final Rule Effective	10/07/21	
Interim Final Rule Comment Period End	12/06/21	
Final Action	06/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Deborah Bryant, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight, MS: W08-134, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 301 492-4293

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RIN: 0938-AU62

Department of Health and Human Services (HHS)	Long-Term Actions
Centers for Medicare & Medicaid Services (CMS)	

115. OMNIBUS COVID-19 HEALTH CARE STAFF VACCINATION (CMS-3415) (SECTION 610 REVIEW) [0938-AU75]

Legal Authority: 42 U.S.C. 1395hh; 42 U.S.C. 1302

Abstract: This interim final rule with comment period revises the infection control requirements that most Medicare- and Medicaid-participating providers and suppliers must meet to participate in the Medicare and Medicaid programs. These changes are necessary to protect the health and safety of residents, clients, patients, and staff and reflect lessons learned as result of the COVID-19 public health emergency. The revisions to the infection control requirements establish COVID-19 vaccination requirements for staff at the included Medicare- and Medicaid-participating providers and suppliers.

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/05/21	86 FR 61555
Interim Final Rule Effective	11/05/21	
Interim Final Rule Comment Period End	01/04/22	
Reviewing Public Comments	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Kim Roche, Nurse, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, MS: C2-21-16, 7500 Security Boulevard, Baltimore, MD 21244

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Email: kim.roche@cms.hhs.gov

RIN: 0938-AU75

Department of Health and Human Services (HHS)	Completed Actions
Centers for Medicare & Medicaid Services (CMS)	

116. DURABLE MEDICAL EQUIPMENT FEE SCHEDULE, ADJUSTMENTS TO RESUME THE TRANSITIONAL 50/50 BLENDED RATES TO PROVIDE RELIEF IN NON-COMPETITIVE BIDDING AREAS (CMS-1687) (COMPLETION OF A SECTION 610 REVIEW) [0938-AT21]

Legal Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)); Pub. L. 114-255, sec. 5004(b), 16007(a) and 16008

Abstract: This final rule responds to public comments on the interim final rule that published May 11, 2018 and extended the end of the transition period from June 30, 2016, to December 31, 2016 for phasing in adjustments to the fee schedule amounts for certain durable medical equipment (DME) and enteral nutrition paid in areas not subject to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). In addition, the interim rule amended the regulation to resume the transition period for items furnished from August 1, 2017, through December 31, 2018. The interim rule also made technical amendments to existing regulations for DMEPOS items and services to exclude infusion drugs used with DME from the DMEPOS CBP.

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/11/18	83 FR 21912
Interim Final Rule Comment Period End	07/09/18	
Continuation Notice	04/26/21	86 FR 21949
Final Action Merged With 0938-AU38 and 0938-AU17	12/28/21	86 FR 73860

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Alexander Ullman, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5-07-26, 7500 Security Boulevard, Baltimore, MD 21244

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Email: alexander.ullman@cms.hhs.gov

RIN: 0938-AT21

117. MOST FAVORED NATION (MFN) MODEL (CMS-5528) (COMPLETION OF A SECTION 610 REVIEW) [0938-AT91]

Legal Authority: Social Security Act, sec. 1115A

Abstract: This final rule rescinds the Most Favored Nation Model interim final rule with comment period that appeared in the November 27, 2020, **Federal Register** .

Timetable:

Action	Date	FR Cite
ANPRM	10/30/18	83 FR 54546
ANPRM Comment Period End	12/31/18	
Interim Final Rule	11/27/20	85 FR 76180
Interim Final Rule Effective	11/27/20	
Interim Final Rule Comment Period End	01/26/21	
NPRM	08/10/21	86 FR 43618
NPRM Comment Period End	10/12/21	
Final Action	12/29/21	86 FR 73986
Final Action Effective	02/28/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Lara Strawbridge, Director, Division of Ambulatory Payment Models, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare and Medicaid Innovation, 7500 Security Boulevard, MS: WB-06-05, Baltimore, MD 21244

Phone: 410 786-7400

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RIN: 0938-AT91

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118. HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS; THE LONG-TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM; AND FY 2022 RATES (CMS-1752) (COMPLETION OF A SECTION 610 REVIEW) [0938-AU44]

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This rule finalizes the remaining policies proposed for the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. These policies include implementation of sections 126, 127, and 131 of the Consolidated Appropriations Act of 2020, and organ acquisition payment policies.

Timetable:

Action	Date	FR Cite
NPRM	05/10/21	86 FR 25070
NPRM Comment Period End	06/28/21	
Final Action	08/13/21	86 FR 44774
Final Action Effective	10/01/21	
Final Action Correction	10/20/21	86 FR 58019
2nd Final Action	12/27/21	86 FR 73416
2nd Final Action Effective	02/25/22	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938-AU44

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